



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,081	10/03/2003	Hans-Michael Dosch	2560.001	3553
21917	7590	02/22/2006	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			LIETO, LOUIS D	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	Application No. 10/679,081	Applicant(s) DOSCH ET AL.	
	Examiner Louis D. Lieto	Art Unit 1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: None.  
 Claim(s) objected to: None.  
 Claim(s) rejected: 2 and 5-7.  
 Claim(s) withdrawn from consideration: 1, 3 and 4.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).  
 13. ☐ Other: \_\_\_\_\_

  
 DEBORAH CROUCH  
 PRIMARY EXAMINER  
 GROUP 1800/636

Continuation of 11. does NOT place the application in condition for allowance because: Applicant has presented arguments traversing the 103 obviousness rejection that was made in the non-final action of 6/08/2005 and extended to new claims 6 and 7 in the final action of 11/03/2005. Applicant's arguments are substantially the same and it is unclear why they were not made in previous replies. Applicant's arguments are not found to be persuasive in overcoming the rejection set forth in the office actions of 6/08/2005 and 11/03/2005.

Applicant's arguments focus on the examiner's arguments about the inherent attributes of the ABBOS peptide. It is noted that applicant's are drawn to treating primary Sjogrens syndrome in any mammal. As previously stated: Applicant's claimed invention is akin to claiming a method of using aspirin to reduce the risk of blood clots. Since people have been taking aspirin for pain for over 100 years for headaches they are at the same time reducing their incidence of blood clots. The methods cannot be separated since they both are dependent only on an inherent property of the aspirin. Similarly the method of treating primary Sjögren's Syndrome is dependent on treating a mammal with ABBOS. When the ABBOS is used to treat the NOD mice of Karges, it obviously also treats any other diseases treatable by ABBOS in these NOD mice, such as primary Sjögren's Syndrome. ABBOS in this context is the equivalent of a chemical compound. Any therapeutic properties are inherent to the sequence and structure of the ABBOS peptide. As previously stated: Karges et al. provides guidance on treatment of NOD mice with the ABBOS mimicry high-affinity peptide, in order to induce T-cell tolerance to ICA69 (Abstract). Further Karges et al. teaches that administration of the ABBOS mimicry peptide reduced diabetes incidence in NOD mice (pg. 1554, col. 1, pgph 1554) and was able to induce cross-tolerance to the Tep69 epitope of ICA69 autoantigen (pg. 1551, Fig. 3). Humphreys-Behr teaches that NOD mice undergo a corresponding loss in exocrine gland function related to lymphocyte infiltrates symptomatic of the pathophysiology of primary Sjögren's Syndrome. Therefore by treating the diabetic mice with the ABBOS peptide Karges obviously has treated their symptoms of primary Sjögren's Syndrome. Since both primary Sjögren's Syndrome and diabetes occurs in these NOD mice and they are both mediated by ICA69 specific T-cells. The induction of tolerance in these T-cells to treat diabetes must also treat primary Sjögren's Syndrome. Therefore the rejection is maintained for reasons of record as stated above and in the office actions of 6/08/2005 and 11/03/2005.